Section XII: 510(k) Summary of Safety and Effectiveness

FEB - 6 2004

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

K033756
page 1 of 1

NAME OF FIRM:
I.T.S. Implantat-Technologie-Systeme GmbH.
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Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME:
Volar Radius Plate with Angular Stability

COMMON NAME:
Fracture Fixation Plating system for fracture fixation of the end of long bones

CLASSIFICATION:
Single/multiple component metallic bone fixation appliances and accessories (see 21 CRF, Sec. 888.3030).

DEVICE PRODUCT CODE: HRS

SUBSTANTIALLY EQUIVALENT DEVICES:
Avanta SCS/V Distal Radius Plate - Volar
Hand Innovations DVR Plate
Synthes Locking Distal Radius System 2.4

DEVICE DESCRIPTION:
The I.T.S. Volar Radius Plate with Angular Stability provides various width 4 and 6 hole standard plates, various width 8, 10, and 12 hole long plates, various length stabilization screws, and various length cortical fixation screws. The volar radius plates are made from CP Titanium according to ASTM F 67-00 and the screws are made from 6-4 Alloyed Titanium according to ASTM F 136-98.

INTENDED USE:
The I.T.S. Volar Radius Plate is used to stabilize distal radius fractures in the wrist with an accurate retention of articular fracture elements.

BASIS OF SUBSTANTIAL EQUIVALENCY:
The I.T.S. Volar Radius Plate is substantially equivalent to the Avanta, Hand Innovations, and Synthes fracture plating systems

SUMMARY OF SAFETY AND EFFECTIVENESS:
The I.T.S. Volar Radius Plate system is shown to be safe and effective for use in fracture fixation of the distal radius in the wrist.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2004

I.T.S. Implantat-Technologie-Systeme GMBH
Al Lippincott
c/o Engineering Consulting Services, Inc.
3150 East 200th Street
Prior Lake, Minnesota 55372

Re: K033756
Trade/Device Name: Volar Radius Plate with Angular Stability
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: November 24, 2003
Received: December 1, 2003

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) NUMBER: k033756

DEVICE NAME: Volar Radius Plate

INDICATIONS FOR USE:

The I.T.S. Volar Radius Plate with Angular Stability is a titanium implant fracture fixation system for distal radius fractures of the wrist.

Indications for Use include comminuted extra and intra-articular distal radius fractures, failed original fracture fixation, osteotomy and repair of a distal radius malunion, and comminuted volar shearing fractures

The I.T.S. Volar Radius Plate system provides immediate stability, rapid recovery, and prompt wrist functionality.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format)

for Mark N Milhern

K033756